

K931220

MAY 22 1986

SAFETY AND EFFECTIVENESS SUMMARY

Classification name : Condom (Rubber) Contraceptive

Classification Number : 85 HIS

Proprietary Name : The device in this 510(K) summary is a spermicidal lubricated condom. The condom will be sold under various trade names including Eros, Iris, Amoret, Galant, Gemini, Brilliant, Casanova and Galla.

Intended Use and Performance Claim : Condoms, when properly used, are an effective way to prevent pregnancy, although no contraceptive can guarantee 100 % effectiveness. They will also reduce the risk of spreading sexually transmitted diseases such as AIDS, syphilis, etc.

Physical Composition : Condoms are manufactured from natural latex type FA. The latex is purchased from traditional territories of Malaysia and is of the highest quality which is tested according to ISO 2004.

Specifications : All specifications for these condoms meet or exceed all ASTM and ISO standards for condoms according to FDA requirements.

Safety Guidelines: When using a condom follow all instructions included with the condom. To assure that the condom will perform to its maximum quality level, follow this safety guideline:

Do Not Use the Condom If:

The external package has visual signs of being tampered with, or shows physical damage possibly due to mishandling.
The individual foil wrapping of the condom is damaged.
The condom itself has damage (a tear or rip, is cracked or dried up or has any deformities as compared to a regular Spermicidal lubricated condom). Any other apparent damage that would cause a suspicion of the loss of integrity to the condom. The condoms should be stored in the cool and dry place.